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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/918,715	08/01/2001	Brad St. Croix	001107.00134	2480
22907	7590	02/09/2005	EXAMINER	
			YAEN, CHRISTOPHER H	
		ART UNIT		PAPER NUMBER
				1642

DATE MAILED: 02/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/918,715	ST. CROIX ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Christopher H Yaen	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11/17/2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10 and 18-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-10 and 18-37 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

**Re: St. Croix et al  
Priority Date: 2 August 2000**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2004 has been entered.
2. The amendment filed 8/18/2004 is acknowledged and entered into the record. Accordingly, claims 11-17 are canceled without prejudice or disclaimer.
3. Claims 1-10, 18-37 are pending and examined on the merits.
4. The Affidavit/Declaration of Kenneth W. Kinzler (herein Kinzler Declaration) filed 8/18/2004 is acknowledged and considered.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections Maintained - 35 USC § 101 and 112, 1<sup>st</sup> paragraph***

6. The rejection of claims 1-10 and 18-37 under 35 USC § 101 and 35 USC § 112, 1<sup>st</sup> paragraph as lacking a specific and substantially well established utility is maintained for the reasons of record. Applicant rebuts the rejection by filing the Kinzler declaration under 37 CFR 1.132. In the Kinzler declaration, Kinzler attests to the fact that TEM 17

is produced in human tumors, that TEM 17 is differentially expressed in tumor tissue, that an anti-TEM 17 antibody was able to bind to tumor vessels *in vivo*, and that TEM 17 specifically binds to cortactin (see declaration and applicant's arguments page 6).

Applicant concludes that antibodies to TEM 17 would thus have a real world utility for inhibiting neoangiogenesis, inhibiting tumor growth, isolating endothelial cells, and to identify tumor endothelium for diagnostic purposes (see page 6). Applicant's arguments have been carefully considered but are not deemed persuasive to overcome the rejection of record.

MPEP 2107 states that when an invention lacks a specific and substantial well-established utility, a rejection under 35 USC 101 and 112, 1<sup>st</sup> paragraph should be applied. It also states that the burden rests with the applicant to "[p]rovide evidence that one of ordinary skill in the art would have recognized that the identified specific and substantial utility was well-established *at the time of filing*." In the instant case, applicant relies on the Kinzler declaration to establish a specific and substantial utility for the instantly claimed anti-TEM 17 antibodies. The evidence provided by the Kinzler Declaration was based on the subsequent discovery of TEM-17 protein (both localization and expression), the ability of antibodies to bind to TEM-17, and a TEM 17 binding partner (i.e. cortactin). At the time of filing, applicant only provided evidence of mRNA expression through SAGE analysis and failed to provide evidence or disclosure of the TEM-17 protein and its corresponding antibodies. Thus no specific or substantial utility was applied to the protein or antibodies that are capable of binding to said protein. Therefore, at the time of filing, applicant did not recognize that the TEM-17 protein was

expressed in human tumor tissue, that TEM-17 protein is differentially expressed in tumor tissue, that antibodies to TEM-17 were able to label tumor vessels, and that TEM-17 specifically binds to cortactin. Therefore utilities related thereto (i.e. inhibit neoangiogenesis, inhibit tumor growth, to isolate endothelial cells, and to identify tumor endothelial) were not realized at the time of filing and therefore a specific or substantial utility for the claimed TEM-17 protein or antibodies that bind was not readily apparent to the applicant at the time of filing. Thus the rejection under 35 USC 101 and 112, 1<sup>st</sup> paragraph as lacking a specific and substantially well established utility is maintained for the reasons of record.

Accordingly, the declaration of Kenneth W Kinzler under 37 CFR 1.132 filed 8/18/2004 is insufficient to overcome the rejection of claims 1-10 and 18-37 based upon a lack of utility rejection previously set forth.

### ***New Arguments***

#### ***Claim Rejections - 35 USC § 112, 1<sup>st</sup> paragraph***

7. Claims 26-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. THIS IS A NEW MATTER REJECTION.  
Claims 26-30 specifically recite antibodies that bind to residues 134-244 or 280-344 of the TEM-17 protein. The specific limitations set forth in the claims do not find support in

the specification as filed. The specification provides support for antibodies that bind to the extracellular domain of TEM17, which is defined as amino acids 18-427 (see page 32). Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

### **Conclusion**

No claim is allowed.

This is a continuation examination of applicant's earlier Application No. 09/918715. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

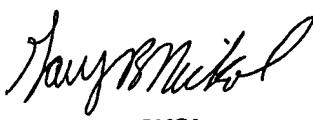
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen  
Art Unit 1642  
January 31, 2005

  
GARY NICKOL  
PRIMARY EXAMINER